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Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	09/801,443
Filing Date	03/07/2001
First Named Inventor	Suneel K. GUPTA
Group Art Unit	1615
Examiner Name	TRAN, Susan T
Attorney Docket Number	ARC 2863 N1

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
S.T.	AA	2,799,241		WURSTER	07/16/1957	
	AB	3,845,770		THEEUWES et al.	11/05/1974	
	AC	3,916,899		THEEUWES et al.	11/04/1975	
	AD	4,063,064		SAUNDERS et al.	12/13/1977	
	AE	4,088,864		THEEUWES et al.	05/09/1978	
	AF	4,200,098		AYER et al.	04/29/1980	
	AG	4,285,987		AYER et al.	08/25/1981	
	AH	4,327,725		CORTESE et al.	05/04/1982	
	AI	4,612,008		WONG et al.	09/16/1986	
	AJ	4,783,337		WONG et al.	11/08/1988	
	AK	4,816,263		AYER et al.	03/28/1989	
	AL	4,863,456		STEPHENS et al.	09/05/1989	
	AM	4,902,514		BARCLAY et al.	02/20/1990	
	AN	5,480,651		CALLAWAY	01/02/1996	
	AO	5,674,895		GUITTARD et al.	10/07/1997	
	AP	5,840,754		GUITTARD et al.	11/24/1998	
	AQ	6,124,335		GUITTARD et al.	09/26/2000	
S.T.	AR	6,262,115		GUITTARD et al.	07/17/2001	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	†
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
S.T.	AS	WO	96/12477	A1	LEIRAS OY (Rantala et al.)	05/02/1996		
S.T.	AT	WO	98/43555	A1	Point Biomedical Corp.	10/08/1998		

Examiner Signature	S.T.	Date Considered	9/22/05
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
2.T	AU	BENZIGER, David P. et al., "Differential Effects of Food on the Bioavailability of Controlled-Release Oxycodone Tablets and Immediate-Release Oxycodone Solution", <u>Journal of Pharmaceutical Sciences</u> , 85(4):407-410, 1996	
	AV	CHUNG, Menger et al., "Clinical Pharmacokinetics of Nifedipine Gastrointestinal Therapeutic System", <u>The American Journal of Medicine</u> , 83:10-14, 1987	
	AW	GRAFTON, P., "General principles for designing with plastics", <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969.	
	AX	LUKKARI, Eeva, et al., Effect of time interval between food and drug ingestion on the absorption of oxybutynin from a controlled-release tablet, <u>Pharmacol. &amp; Toxicology</u> , 81(1):31-34, 1997	
	AY	LUKKARI, Eeva et al., "Effect of food on the bioavailability of oxybutynin from a controlled release tablet," <u>Eur. J. Pharmacology</u> , 50:221-223, 1996	
	AZ	FELMEISTER, Alvin, "Powders," <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Mack Publishing Co., Ch. 86, pp. 1626-1648, 1970.	
	BA	MASSAD, Charlotte A. et al., "The pharmacokinetics of intravesical and oral oxybutynin chloride", <u>J. Urology</u> , 148:595-597, August 1992.	
	BB	NILSSON, Carl Gustaf et al., "Comparison of a 10-mg controlled release oxybutynin tablet with a 5-mg oxybutynin tablet in urge incontinent patients", <u>Nerol Urology</u> , 16(6):533-542, 1997.	
	BC	SATHYAN, Gayatri et al., "Effect of OROS® controlled-release delivery on the pharmacokinetics and pharmacodynamics of oxybutynin chloride", <u>Br. J. Clin. Pharmacol.</u> , 52:409-417, 2001.	
	BD	WALDECK, Kristen et al., "Comparison of oxybutynin and its active metabolite, N-desethyl-oxybutynin, in the human detrusor and parotid gland", <u>J. Urology</u> , 157(3):1093-1097, 1997.	
	BE	WPI / Derwent Database, "Pharmaceutical preparation prolong action urine incontinence comp rise sustained release chloride pharmaceutical composition sustained release coating film non water soluble polymer ethylcellulose", Abstract of JP 05-339151, (Kodama KK), 12/21/1993	
	BF	WURSTER, Dale E., "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc.</u> , 48(8):451-454, 1959	
	BG	WURSTER, Dale E., "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc.</u> , 49(2):82-84, 1960	
2.T	BH	YANG, Libo et al., "Modulation of Diclofenac Release From a Totally Soluble Controlled Release Drug Delivery System", <u>Journal of Controlled Release</u> , 44:135-140, 1997.	

Examiner Signature	2.T	Date Considered	9/22/05
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